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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,645	01/24/2002	Anne Gillian Welch	9013.31	8639
20792 7590 12/08/2010 MYERS BIGEL SIBLEY & SAJOVEC PO BOX 37428 RALEIGH, NC 27627				
EXAMINER				
BOESEN, AGNIESZKA				
ART UNIT		PAPER NUMBER		
1648				
MAIL DATE		DELIVERY MODE		
12/08/2010		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

09/889,645

**Applicant(s)**

WELCH ET AL.

**Examiner**

AGNIESZKA BOESEN

**Art Unit**

1648

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 September 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3,6-10,12-16,25,28 and 31-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,6-10,12-16,25,28 and 31-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The Amendment filed September 16, 2010 in response to the Office Action of June 16, 2010 is acknowledged and has been entered. Claims 1, 3, 6-10, 12-16, 25, 28, and 31-39 are pending and under examination in this Office action.

#### ***Claim Rejections - 35 USC § 101***

Rejection of Claim 14 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter **is withdrawn** in view of Applicant's amendment.

#### ***Double Patenting Warning***

Applicant is advised that should claim 1 be found allowable, claim 31 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Applicant states that Applicant will resolve any outstanding issues regarding these claims as appropriate.

#### ***Claim Rejections - 35 USC § 103***

Rejection of Claims 1, 3, 6-10, 12-16, 25, 28 and 31-39 under 35 U.S.C. 103(a) as being unpatentable over Morgenhalter et al. (US Patent 6,407,212 B1) in view of Breitenbach et al. (US Patent 6,083,408) **is withdrawn** in view of Applicant's arguments.

#### ***New Rejections***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 1, 3, 6-10, 12-16, 25, 28 and 31-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerba et al. (Applied and Environmental Microbiology, 1985, p. 1375-1377) in view of Brown et al. (Transfusion, 1998, Vol. 38, p. 810-816).**

Gerba teaches method of removal of *Escherichia coli* and endotoxin from tap water-aqueous liquid, comprising passing the water through a 3.9 cm<sup>2</sup> depth filter formed of a matrix comprising a cellulose binder and kieselguhr (diatomaceous earth) (see Materials and Methods). Gerba teaches that endotoxin removal was highly effective at pH from 4.0 to 7.5 (see page 1376).

Gerba discusses the pore size however Gerba does not provide the number of the pore size. However since Gerba is using the same material in the filter, the kieselguhr and is able to retain the endotoxin particles and pass water, it would have been obvious that Gerba's filter will retain prions and pass the liquid. It would have been within the skill of ordinary artisan to vary and adjust the pore size depending on the liquid being passed through the filter. It would have been obvious to optimize the filter pore size, the filter thickness and the filter permeability. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). Optimization of parameters is a

routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention.

Gerba does not teach treating the filter with ethanol however it would have been obvious to do that for the disinfection purposes. Gerba does not teach using the filter to remove prions from blood products such plasma.

Brown teaches methods of fractionation of plasma to remove infectious prions (see Materials and Methods). Brown teaches blood plasma product subject to prion removal. Brown teaches blood plasma product albumin (see page 815).

However, it would have been *prima facie* obvious to provide the methods of removal of infectious prions from plasma taught by Brown using Gerba's depth filter comprising cellulose and kieselguhr because Gerba teaches that his depth filter allows for enhanced removal of bacteria and bacterial endotoxin from solution (see page 1375). It would have been obvious to provide a single use filter so that any contaminants are not transferred from one plasma product to another.

All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

**Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by Brown et al. (Transfusion, 1998, Vol. 38, p. 810-816).**

Brown discloses blood plasma subjected to prion removal (see the entire document). The Examiner notes that the product by process limitations of independent claim 1 is not limiting.

The product disclosed by the prior art is identical to the claimed product, (even though it is made by a somewhat different process/the prior art is silent on the method of making). There is no evidence to show that the claimed process imparts any patentable distinction between the claimed product and that of the prior art. M.P.E.P. Section 2113 states that: “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production.

Thus by disclosure Brown anticipates the present claims.

***Conclusion***

No claims are allowed.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Zachariah Lucas can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Agnieszka Boesen/  
Examiner, Art Unit 1648